MEDICAL RECORD	SPECIAL EXEMPTION FROM RESEARCH PROTOCOL	Protocol No. Initiating Office No. (NCI ONLY)

INSTRUCTIONS Principal Investigator:

1 Obtain Branch Chief, Institute Clinical Director and IRB Chair approval signatures.
2. Attach a **copy** of the NIH-2514-1 Consent to Participate in a Clinical Research Study. The consent must have been signed by the patient.
3. Forward the NIH-2702 Special Exemption from Research Protocol form to the Director, CC (Building 10, Room 2C146) or his designee for final approval and signature.
4. You will be notified by the Office of the Director, CC (Building 10, Room 2C146) or his designee of the APPROVAL/DISAPPROVAL of the NIH-2702. You may obtain a copy of the approved NIH-2702 either by having it picked up from Building 10, Room 2C146, or by requesting that a copy be mailed to you.
5. Submit a 30-day follow-up to your Institute Clinical Director for all approved exemptions.

Director, CC (or his designee):

1. Notify Principal Investigator of APPROVAL/DISAPPROVAL. Return one copy of the approved NIH-2702 to the Principal Investigator.
2. Forward one copy each to: Chief, Outpatient Department, CC (Building 10, Room 1C243); Pharmacy Department, CC (Building 10, Room 1N257).
3. Forward original NIH-2702 to Protocol Coordination Service Center, MRD, CC (Building 10, Room 1S231B). Original will be filed in patient's medical record.

DIAGNOSIS	SEX ☐ Male ☐ Female	DATE OF BIRTH Mo Day Yr
	NATURE OF REQUEST ☐ Single Patient Single Use ☐ Emergency Use IND ☐ Treatment IND	

CLINICAL SUMMARY (To include a brief history, present status of patient, diagnosis, relevant lab data and *"reason for requesting special exemption")*

PRINCIPAL INVESTIGATOR

Principal Investigator _____ Date _____

Building_____ Room_____ Telephone_____ Institute_____

APPROVALS

Branch Chief _____ Date _____

Institute Clinical Director _____ Date _____

IRB Chair _____ Date _____

Director, Clinical Center or designee _____ Date _____

This exemption is valid for one year from the signature date of the Director, Clinical Center or designee. If a patient is to remain on the special exemption for longer than one year, a renewal exemption form must be submitted for approval.

EXEMPTION STATUS

☐ SINGLE PATIENT SINGLE USE
(Clinical Center Policy)

This mechanism allows a patient to receive the IND even though the patient does not quite meet the specified protocol entry criteria, for example, being 63 instead of less than 60 years of age, or having a serum bilirubin of 1.2 when the entry criterion is less than 1.0. The drug companies that sponsor such protocols generally discourage this mechanism because deviating from careful selection rules can damage the study and reduce its value.

This mechanism also can allow a patient to be given an IND to "treat" a serious illness when no satisfactory alternative therapy is

available. IND's under trial at the CC or elsewhere may be used for the exemption. The physician ordering the drug must have the approval of the sponsor. The protocol consent document used in the ongoing trial can usually be used for these patients, but they must be informed that they are *not* protocol participants. FDA expects a full reporting of the outcome.

PROTOCOL NO. _____

Total Previous Exemptions
To This Protocol: _____

NOTE: Single Patient Single Use is to be denoted by a Protocol Number as follows:
a) last two digits of the present fiscal year
b) institute abbreviation
c) "1234" for Single Patient Single Use

For Example: 01-CH-1234

☐ EMERGENCY USE IND
(FDA Rule)

A test article may be used for a single patient in a life-threatening situation when no standard acceptable treatment is available and when the time for filing for an IND and obtaining IRB approval in the usual manner is insufficient. A temporary IND is granted by FDA, usually by telephone, with the understanding that the sponsor will submit a proper IND. Emergency use must be reported promptly to the IRB Chair. Further use of the test article In the institution is subject to IRB review.

PROTOCOL NO. _____

Total Previous Exemptions
To This Protocol: _____

NOTE: Emergency Use IND is to be denoted by a Protocol Number as follows:
a) last two digits of the present fiscal year
b) institute abbreviation
c) "9980" for Emergency Use IND

For Example: 01-CH-9980

☐ TREATMENT IND
(FDA Rule)

This mechanism – added by FDA in 1987 and first used at the CC

in December 1987 for ifosfamide and mesna in the treatment of refractory germ cell carcinoma – is intended to make an IND available to patients with a serious or immediately life-threatening

disease. At the same time the sponsor can learn some information about efficacy and toxicity. Criteria for permitting the use of a treatment IND are as follows: the disease is serious or immediately life-threatening; no satisfactory alternative is available; and the drug is under study in a controlled clinical trial under an IND in effect for the trial; or all clinical trails have been completed and the sponsor of the clinical trail is actively pursuing marketing approval.

The sponsor develops a treatment IND protocol and makes the drug available to licensed practitioners ("investigators"), who commit to the protocol-described handling of the test article for administration to patients. In the CC, the IRB approves the protocol and the protocol consent document, which must pass through the usual protocol track until a protocol number is assigned.

PROTOCOL NO. _____

Total Previous Exemptions
To This Protocol: _____

NOTE: Treatment IND is to be denoted by a Protocol Number as follows:
a) last two digits of the present fiscal year
b) institute abbreviation
c) "9990" for Treatment IND

For Example: 01-CH-9990

JUSTIFICATION INFORMATION

☐ YES ☐ NO Is this special exemption a **renewal** for a previously approved special exemption?

☐ YES ☐ NO Is this patient **eligible** for any institute research study related to this disease/condition?

☐ YES ☐ NO Have **standard treatments been exhausted** for this patient?

☐ YES ☐ NO Is there objective evidence that the investigational drug therapy/technique is of **potential benefit** in the disease/condition for which the request is being made? (NOTE: There should be sufficient data available to provide a reasonable expectation that the agent will prolong survival or improve the quality of life in a cohort of similar patients so treated.)

☐ YES ☐ NO Is the request for utilization of a **commercially available** drug and/or combination of drugs?

☐ YES ☐ NO Has this drug, drug combination, dosage, schedule and/or route of administration been **approved** by the **FDA**?

☐ YES ☐ NO Do you plan to use data resulting from the treatment of this patient in a scientific publication? If "YES," please provide rationale for inclusion of these data:

Comments:

Please specify the objective evidence (e.g., in vitro, animal, human) which indicates that this drug/therapy/technique would be of potential direct benefit to this patient:

CONSENT

☐ YES ☐ NO If the patient is an adult, is she/he capable of providing informed consent? If "NO," who has given consent on behalf of the patient?

_____
(Name and Relationship)

☐ ADULT: Please attach a copy of the consent document "NIH-2514-1, Consent to Participate in a Clinical Research Study" signed by the patient for the requested exemption.

☐ MINOR: Please attach a copy of the consent document "NIH-2514-1, Consent to participate in a Clinical Research Study" signed by the parent (if other than parent, specify relationship) and "NIH-2514-2, Minor Patient's Assent to Participate in a Clinical Research Study" signed by the patient for the requested exemption.

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REGIMEN

Please outline your planned regimen for this patient for this special exemption:

FOLLOW-UP

Please plan to submit a 30-day follow-up evaluation describing the clinical course of this patient following this exemption.